Supreme Court, U.S.
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No. _____

In The

Supreme Court of the United States

October Term, 1997

CRITIKON, INC.,

Cross-Petitioner,

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,

Cross-Respondent.

On Conditional Cross-Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Did the Court of Appeals for the Federal Circuit err by not following its *en banc* decision in *Kingsdown Medical Consultants v. Hollister, Inc.*, 863 F.2d 867 (Fed.Cir. 1988), holding that as a matter of law a patent applicant's gross negligence does not give rise to sufficient culpability to hold a patent unenforceable on the ground of inequitable conduct?

2. Did the Court of Appeals for the Federal Circuit improperly set aside the district court's fact findings without giving due regard to the district court's findings as required by Rule 52(a), Fed.R.Civ.P.?

STATEMENT PURSUANT TO RULE 29.6

Critikon, Inc., the conditional cross-petitioner here, was the plaintiff-cross appellant below. The affiliates of Critikon, Inc. are Johnson & Johnson, Inc. and Johnson & Johnson Medical, Inc. The successor in interest of Critikon, Inc. is Johnson & Johnson Medical, Inc. Becton Dickinson Vascular Access, Inc., the cross-respondent here, was the defendant-appellant below and is the wholly owned subsidiary of Becton Dickinson and Company.

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CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Critikon, Inc. ("Critikon") submits this conditional cross-petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). Becton Dickinson Vascular Access, Inc. ("Becton Dickinson") submitted a petition for a writ of certiorari in this action on December 23, 1997, docketed on January 6, 1998 as No. 97-1095 (hereinafter "Becton Dickinson's petition"). Critikon opposes Becton Dickinson's petition in a separately filed opposition. However, in the event that Becton Dickinson's petition is granted, Critikon believes that the instant conditional cross-petition should also be granted.

OPINIONS BELOW

The August 12, 1997 opinion of the Federal Circuit is reported at 120 F.3d 1253 (Fed.Cir. 1997), and is reproduced beginning at Appendix page 2a of Becton Dickinson's petition. The July 18, 1994 memorandum opinion of the district court is reproduced beginning at Appendix page 19a of Becton Dickinson's petition.

JURISDICTION

The Federal Circuit denied petitions for rehearing and suggestions for rehearing *en banc* on September 24, 1997. Becton Dickinson's petition for a writ of certiorari was docketed on January 6, 1998, as No. 97-1095. The

instant cross-petition is timely filed pursuant to Rule 12.5, Sup.Ct.R. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Rule 52(a) of Title 28, Fed.R.Civ.P., provides in pertinent part:

> Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witness. . . .

STATEMENT OF THE CASE

In this action for patent infringement, Critikon charged Becton Dickinson with infringing two patents, U.S. Patent No. 4,952,207 (and the reissue of that patent, No. RE 34,416) issued to Lemieux (hereinafter the "Lemieux patents"), and U.S. Patent No. 4,978,344, issued to Dombrowski (hereinafter the "Dombrowski patent"). The Lemieux and Dombrowski patents were found valid by the Federal Circuit and the Federal Circuit found that Becton Dickinson willfully infringed both patents.

The subject of this petition is directed to the Federal Circuit's erroneous conclusion that the Lemieux patents are unenforceable due to the alleged inequitable conduct – *i.e.*, fraud – practiced on the United States Patent and Trademark Office (hereinafter "PTO") by the Critikon attorneys that prosecuted the Lemieux patents.

I. Background

The Lemieux patents are directed to medical devices called intravenous catheters. Intravenous catheters consist of thin plastic tubes that are inserted into a hospital patient's veins so that medicinal fluids can be introduced into the body. (3a, 21a). To permit insertion into a vein, catheters are mounted over steel introducer needles. After the catheter-needle assembly is inserted by a healthcare worker, the needle is withdrawn, leaving the catheter within the vein. (3a, 21a). This procedure, however, subjects the healthcare worker to the danger of accidental needlesticks from the exposed needle. Due to the increased risk of exposure to AIDS by way of accidental needlesticks, the demand for improved safety catheters became the overwhelming issue in hospitals in the late 1980's.

After extensive research and development, Critikon invented the safety catheter described in the Lemieux patents. The Lemieux safety catheter has a "needle guard" that is positioned over the tip of the needle as the needle is withdrawn from the catheter to protect healthcare workers from accidental needlesticks. (3a, 23a). As a result of its research and development, Critikon was the very first company to introduce a viable, commercial safety catheter for use in hospitals, a product referred to as the ProtectIV® safety catheter system. Over the years, Critikon's ProtectIV® safety catheter has saved scores of lives by eliminating the possibility of accidental needlesticks.

II. The Proceedings In The District Court

After a highly fact intensive case involving over 1300 pages of trial testimony, 8000 pages of deposition testimony, and 1000 exhibits, the district court held that Becton Dickinson had wholly failed to prove that there was any inequitable conduct associated with Critikon's prosecution of the Lemieux patents. In the trial court, Becton Dickinson argued that Critikon's attorneys had intentionally withheld a prior art patent, the McDonald '718 patent (hereinafter, "the McDonald patent"), from the PTO during the prosecution of the Lemieux patents. (50a).

Critikon responded by showing that Critikon's failure to cite the McDonald patent to the PTO was not done with any intent to mislead or deceive the PTO, and that, in any event, the McDonald patent was not a material reference. (51a). The district court agreed with Critikon. On the issue of intent, the district court specifically found that Critikon's actions were "not intentional nor designed to mislead the patent examiner." (51a). In so holding, the district court was persuaded by the testimony of Critikon's witnesses establishing that the McDonald patent was "substantially different than . . . the Lemieux patents." (52a). The district court's conclusion on the intent issue was based not only on the credibility of Critikon's witnesses, (52a), but also on the lack of credibility of Becton Dickinson's expert witness, Mr. Fischell, who was found by the district court to be "ambivalent" and unable to withstand cross-examination. (26a-27a, 35a, 39a, 46a-47a).

On the materiality issue, the district court again agreed with Critikon. Specifically, the district court was "persuaded by the testimony of both expert witnesses that the McDonald patent teaches a device that is substantially different than that contemplated by the Lemieux patents." (51a-52a). This conclusion, once again, was grounded in the district court's credibility findings, and on the admissions of Becton Dickinson's expert witness, Mr. Fischell. Mr. Fischell testified that the McDonald patent was significantly different from the Lemieux patents. He freely admitted that the McDonald patent was "complex," "expensive," not commercially usable as compared to the far more practical and less expensive design of Lemieux, and thus, not material to the patentability of Lemieux.

III. The Federal Circuit Decision

On appeal, the Federal Circuit reversed the district court and found that Critikon had committed inequitable conduct in the prosecution of the Lemieux patents. In finding wrongful intent, the Federal Circuit did not find that there was any actual, specific intent to deceive. Rather, the Federal Circuit improperly based its finding of wrongful intent not on what Critikon knew, but rather on what it *"should have known."* (emphasis added). (6a). Based on that erroneous legal standard, the Federal Circuit overturned the district court. In doing so, the Federal Circuit not only misstated the law, but also erroneously rejected the district court's findings and credibility determinations on the issue of intent. (8a). On the issue of materiality, the Federal Circuit again rejected the district court findings on credibility, and in reversing the district

court, improperly relied exclusively on the thoroughly discredited testimony of Mr. Fischell. (*Compare* 10a-11a *with* 26a-27a, 35a, 39a).

REASONS FOR GRANTING THE PETITION

I. The Court Of Appeals Erred By Not Following Its Own *En Banc* Decision In *Kingsdown Medical*

Congress created the Federal Circuit for the purpose of establishing a uniform body of patent law. After the creation of the Federal Circuit, there was considerable disagreement within that Court as to what legal standard governs the level of wrongful intent needed for a finding of inequitable conduct. In one line of cases, the Federal Circuit held that gross negligence alone was sufficient to establish the required degree of culpability. *See, e.g., Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed.Cir. 1984). Indeed, the *Driscoll* court explicitly held that wrongful intent can be found where an applicant "should have known" that a reference was material. *Driscoll*, 731 F.2d at 885. In another line of cases, the Federal Circuit held that gross negligence was insufficient as a matter of law to support a finding of inequitable conduct. *See, e.g., In re Harita*, 847 F.2d 801, 809 (Fed.Cir. 1988); *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 n. 9 (Fed.Cir. 1987).

As is often the case when diverging rules of law appear, one emerged as the clear winner in the Federal Circuit's *en banc* decision in *Kingsdown Medical Consultants v. Hollister, Inc.*, 863 F.2d 867 (Fed.Cir. 1988). In *Kingsdown*, after a thorough analysis of the conflicting precedents, the Federal Circuit rejected the line of cases

holding that "gross negligence" was sufficient to support a finding of wrongful intent and, in doing so, specifically cited and rejected the legal standard set forth in *Driscoll*. 863 F.2d at 876. Rather, the Federal Circuit held in *Molins PLC v. Textron*, 48 F.3d 1172 (Fed.Cir. 1995), that a "specific intent" to withhold "a known material" reference is necessary before inequitable conduct can be found. 48 F.3d at 1181.

Since *Kingsdown*, and until the Federal Circuit's decision in this case, the legal standard governing the level of intent necessary to find inequitable conduct was well-settled. *See, e.g., Herbert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed.Cir. 1996); *Scripps Clinic & Research Found. v. Genetech, Inc.*, 927 F.2d 1565, 1573 (Fed.Cir. 1991); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed.Cir. 1990); *Hoffman-La Roche v. Lemmon Co.*, 906 F.2d 684, 688 (Fed.Cir. 1990).

In this case, however, the *Critikon* panel violated the settled law of *Kingsdown* by clearly misstating the law and by relying on *Driscoll*. The Federal Circuit held:

> [I]ntent may be inferred where a patent applicant knew, *or should have know*[*n*], that withheld information would be material to the PTO's consideration of the patent application. *Driscoll v. Cebalo* [citation omitted].

(6a) (emphasis added). Plainly, the *Critikon* panel erred in failing to follow the rule of *Kingsdown*, and further erred in reverting to the discredited "should have known" standard of *Driscoll*.

The Federal Circuit disregarded nearly nine years of consistent precedent, it ignored its own *en banc* decision

in *Kingsdown*, and it clearly erred in resurrecting the long rejected rule of *Driscoll*. This abrupt and unexplained change in direction has created a state of uncertainty in the law, an uncertainty that has widespread adverse ramifications justifying this Court's review.

At the time the Federal Circuit was created, the importance of a uniform body of patent law was universally recognized. *Markman v. Westview Instr., Inc.*, 517 U.S. 370, ___, 116 S.Ct. 1384, 1396 (1996). Since that time, technological advances have underscored the importance of patent protection, and likewise, the importance of some reasonable measure of predictability in knowing when that protection might be lost on account of a finding of inequitable conduct. This issue is of special importance because the Federal Circuit has the exclusive jurisdiction over appeals from all United States District Courts in patent cases. *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89, 113 S.Ct. 1967, 1971 (1993).

When there is significant disagreement between two lines of Federal Circuit cases, as there is here, the confusion caused by the inconsistent decisions affects inventors and investors, as well as the public that can attain significant benefits from research and development that is based on the ability to obtain sound, enforceable patent protection. *See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, ___ U.S. ___, ___, 117 S.Ct. 1040, 1045 (1997). For all of these reasons, this Court should grant the instant petition for a writ of certiorari.

II. The Federal Circuit Failed To Follow Rule 52(a), Fed.R.Civ.P.

When reviewing a district court's findings of fact, Rule 52(a) of the Federal Rules of Civil Procedure provides:

> Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witness.

This Court has held that Rule 52(a), Fed.R.Civ.P., means that if the district court's account of the evidence is plausible in light of the entire record, the district court's decision must stand. *Anderson v. City of Bessemer City*, 470 U.S. 564, 573-4, 105 S.Ct. 1504, 1511 (1985). An appellate court may not substitute its own interpretation of the facts in place of those found by the district court, and it is particularly inappropriate for an appellate court to draw sinister conclusions from actions that the district court found innocent. *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 857-858, 102 S.Ct. 2182, 2190 (1982) (*citing United States v. Real Estate Bds.*, 339 U.S. 485, 495, 70 S.Ct. 711, 717 (1950)). In sum, an appellate court cannot reverse the findings of the trier of fact simply because it is convinced that it would have decided the case differently. *Anderson*, 470 U.S. at 573-4, 105 S.Ct. at 1511.

The Federal Circuit plainly violated Rule 52(a) by substituting its own findings for those of the district court when it reversed the district court's finding of no inequitable conduct. Indeed, the Federal Circuit never held the district court's factual determinations to be

"clearly erroneous" as required by Rule 52(a), Fed.R.Civ.P. Rather, the Federal Circuit improperly substituted its own findings for those of the district court.

On the intent issue, the Federal Circuit held that "[o]ur review of the record leads us to conclude that Critikon" intended to mislead the PTO. (6a). But the Federal Circuit did so without showing any deference at all to the district court's findings that, based on a careful weighing of the testimony, Critikon's actions were "not designed to mislead the patent examiner." (51a-52a). The Federal Circuit clearly violated Rule 52(a), Fed.R.Civ.P., by disregarding the district court's findings that Critikon's actions were innocent and instead wrongly substituting its own interpretation of the facts by finding the innocent actions of Critikon to be far "more sinister" than the district court believed them to be. *See Inwood Labs.*, 456 U.S. at 857-58, 102 S.Ct. at 2190. At best, the Federal Circuit's view of the evidence is as plausible as the district court's view, in which case "the [district court's] choice . . . cannot be clearly erroneous." *Anderson*, 470 U.S. at 574, 105 S.Ct. at 1511.

On the issue of materiality, the district court's finding that the McDonald patent was not material was explicitly based on the district court's findings concerning the credibility of the parties' expert witnesses. The district court, after hearing the testimony and cross-examination of the parties' expert witnesses, was "persuaded by the testimony of both expert witnesses that the McDonald patent teaches a device that is substantially different than that contemplated in the Lemieux patents." (51a-52a). In these circumstances, this Court has stated that when factual findings are based on the credibility of witnesses:

> Rule 52(a) demands even greater deference to the trial court's findings; for only the trial judge can be aware of the variations in demeanor and tone of voice that bear so heavily on the listener's understanding of and belief in what is said.

Anderson, 470 U.S. at 575, 105 S.Ct. at 1512. Moreover, according "greater deference" to a district court's findings is especially appropriate where those findings are based, as they are here, on the selection of "the testimony of one of two or more witnesses, each of whom has told a coherent and facially plausible story. . . . " *Id.* When a trial judge makes this type of determination, as he did here, there "can virtually never be clear error." *Id.*

The Federal Circuit, however, afforded the district court's decision no deference by finding that the McDonald patent was material to the patentability of the Lemieux patents. In making its materiality determination, the Federal Circuit relied on the testimony of Mr. Fischell, Becton Dickinson's expert witness, (10a-11a), who the district court found was wholly lacking in credibility. (26a-28a, 34a-35a, 39a, 43a-44a, 50a-52a). Specifically, the district court found that Mr. Fischell was frequently ambivalent and wholly unable to withstand cross-examination. (26a-28a, 34a-35a, 39a, 43a-44a, 50a-52a). By relying on a witness that the district court found to be completely lacking in credibility and disregarding the witnesses found to be credible, the Federal Circuit clearly violated Rule 52(a), Fed.R.Civ.P., warranting the grant of certiorari by this Court.

This is not a case involving mere factual error. Rather, it is a case where the court below wholly disregarded the appropriate standard of review that governs all of the United States Courts of Appeals. When, as in this case, the appellate court misapprehends and misapplies the clearly erroneous standard and fails to expressly find that the district court's findings were clearly erroneous, this Court should grant certiorari. *Citibank, N.A. v. Wells Fargo Asia, Ltd.*, 495 U.S. 660, 668, 110 S.Ct. 2034, 2039 (1990); *Anderson*, 470 U.S. at 566, 105 S.Ct. at 1508; *Inwood Labs.*, 456 U.S. at 853, 102 S.Ct. at 2188; *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 108, 89 S.Ct. 1562, 1568 (1969).

CONCLUSION

For the foregoing reasons, Critikon's conditional cross-petition for a writ of certiorari should be granted.

February 5, 1998

Respectfully Submitted,

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BRIEF IN OPPOSITION

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RULE 29.6 STATEMENT

In accordance with Rule 29.6, Sup.Ct.R., petitioner/cross-respondent Becton Dickinson Vascular Access, Inc. refers to page ii of the conditional cross-petition submitted by respondent/cross-petitioner Critikon, Inc.

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FMC Corp. v. *Manitowoc Co.*,
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BRIEF IN OPPOSITION

SUMMARY OF ARGUMENT

This is not a case where a court of appeals has reversed a district court's findings "simply because it is convinced it would have decided the case differently" (Cross-Petition at 9). This is not a case where a court of appeals is "wrongly substituting its own interpretation of the facts" (*Id.* at 10). This is not a case where the court of appeals "rejected the district court's findings on credibility, and . . . improperly relied exclusively on . . . thoroughly discredited testimony" (*id.* at 5-6) "without showing any deference at all to the district court's findings" (*Id.* at 10).

This is a case where the evidence of record clearly establishes that the Lemieux patent was procured through inequitable conduct, but the District Court's findings were erroneously based on an incomplete consideration of that evidence. The District Court overlooked evidence of record demonstrating that the withheld McDonald patent disclosed the features considered by the patent examiner to be the "point of novelty" of the Lemieux patent. The District Court also misapprehended the scope of a patent applicant's duty under 37 C.F.R. § 1.56(a) and thus overlooked cross-petitioner Critikon's unexplained failure to report this litigation — and the charge of inequitable conduct based on Critikon's failure to disclose the McDonald patent — during proceedings to reissue the Lemieux patent.

The Federal Circuit properly performed its appellate function in correcting the District Court's erroneous views of materiality and intent and in applying the proper standards to the undisputed facts of record. For all these reasons, as set forth more fully below, the conditional cross-petition should be denied.

STATEMENT OF THE CASE

I. Background

Intravenous catheters consist of thin plastic tubes that are inserted into veins so that fluids can be introduced into the body. A hub at one end of the catheter tube allows connection to the fluid delivery system. To enable insertion into a vein, catheters are mounted over introducer needles (3a, 21a).

The Lemieux patent is directed to safety catheters. Safety catheters have a "needle guard" that is positioned over the tip of the introducer needle when the needle is withdrawn from the catheter. The needle guard protects health care workers from accidental needle sticks (3a, 21a).

Early safety catheter designs required health care workers to position the needle guard over the needle tip by manually sliding it along the needle as the needle is withdrawn from

the catheter. Michael McDonald, a paramedic in Chicago, recognized the danger inherent in the manual positioning step and invented a technique that automatically positions the needle guard over the needle tip. The heart of his invention was a "retaining" or locking means that: (a) holds the needle guard and catheter hub together while the needle is in the catheter and (b) disengages the guard from the hub only after the needle tip is safely withdrawn from the catheter into the guard (6a).

The safety catheter described in the Lemieux patent uses the same retaining means technique that McDonald invented. Like McDonald, Lemieux automatically positions the needle guard over the tip by using a retaining means that holds the needle guard together with the catheter hub while the needle is withdrawn, and then disengages the needle guard from the catheter hub (23a-24a).

II. Critikon's Inequitable Conduct In Withholding McDonald

As the Federal Circuit's August 12, 1997 Opinion in this case clearly explains, Critikon engaged in inequitable conduct in withholding the McDonald patent during the original Lemieux prosecution and during proceedings to "reissue"* that patent.

First, Critikon not only knew that the retaining means used to automatically position the needle guard was the "point of novelty" of the Lemieux device during prosecution; Critikon specifically relied on that point to obtain allowance:

> Critikon knew that the examiner considered the retaining means a point of novelty of the Lemieux patent. The

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* A patentee may seek to have a patent "reissued" by the Patent and Trademark Office to correct certain defects that may render the patent wholly or partly invalid. 35 U.S.C. § 251. Like the original prosecution process, a reissue procedure is *ex parte* and places the same duty on the applicant to disclose all known information material to patentability (11a-12a). The reissue proceedings for the Lemieux patent concluded seven months after Critikon brought this action (20a).

> examiner was in direct communication with Critikon and reiterated on at least two occasions the importance of the "retaining means" as a point of novelty in the application. During the course of prosecution of the original Lemieux patent, the examiner twice rejected the application's independent claims that did not call for a means for retaining the needle guard together with the catheter hub. Both times, the examiner stated that those claims "lack the structure at the point of novelty to achieve the intended result and are therefore incomplete," and suggested that they be amended to include retaining means for holding the needle guard within the catheter hub until the needle guard was engaged in place over the needle tip (7a).
>
> * * *
>
> . . . Mr. Colletti [Critikon's patent attorney who prosecuted the Lemieux patents] relied on the novelty of the "retaining means" and the automatic positioning of the protective housing in his arguments to gain allowance of the patent application (11a).

Second, Critikon knew that, unlike any other art submitted to the Examiner, the McDonald patent disclosed the retaining means:

> The use of the "retaining means" to achieve automatic positioning is disclosed only in the uncited McDonald patent; it is not disclosed in any other prior art considered by the examiner. . . .
>
> . . . Mr. Fischell [Becton Dickinson's expert] indicated that the key features of McDonald were the automatic positioning and the "retaining means." Mr. Colletti reflected this position, and Critikon's knowledge thereof, when he testified that he could not recall any prior art considered by the examiner who allowed the original Lemieux patent that describes a catheter device with the "retaining means" (10a).

Third, Critikon withheld the McDonald patent with intent to deceive the Examiner:

> Critikon was intimately familiar with the McDonald patent. Both of Critikon's patent counsel who were involved in the prosecution of the Lemieux patents, Mr. Colletti and Mr. York, had reviewed the McDonald patent in detail. On appeal, Critikon argues that Mr. Colletti believed that the reference was not material and that Mr. York had no recollection of the patent. However, at one point Mr. York reviewed the McDonald patent and in handwritten annotations opined that all the claims, except those including the "retaining means," were invalid. Further, there is evidence that he passed these notes on to Mr. Colletti, who cited the McDonald patent to the PTO in several other patent proceedings. If that were not sufficient to infer intent to mislead or deceive, the record indicates that Critikon's counsel was repeatedly confronted with the McDonald patent and its significance over the course of the litigation, which substantially overlapped the Lemieux reissue proceedings (7a).

Fourth, Critikon failed to disclose the pendency of this litigation — and the charge of inequitable conduct — during the reissue proceeding:

> A patent applicant's duty to disclose is not limited to disclosing prior art. A patent applicant must disclose any material information to the PTO. 37 C.F.R. § 1.56(a) (1996). There seems little doubt that the litigation involving the patent in question would be relevant to its reissue proceeding. According to the Manual of Patent Examining Procedure, relevant litigation includes the defenses raised against validity of the patent, or charges of fraud or inequitable conduct in the litigation, which would normally be material to the reissue application. MPEP 2001.06(c) (1994) (11a-12a).

CORRECTION OF MISSTATEMENTS MADE IN CONDITIONAL CROSS-PETITION

In addition to its incomplete statement of the case, the conditional cross-petition includes many serious misstatements. For example, in asserting that the District Court's opinion should not be reversed, Critikon improperly attempts to "insulate [the District Court's] findings from review by denominating them credibility determinations." *Anderson* v. *City of Bessemer City,* 470 U.S. 564, 575, 105 S.Ct. 1504 (1985). In criticizing the Federal Circuit's judgment, Critikon fails to mention an important basis for that judgment: the District Court did not consider Critikon's failure to report this litigation — and the charge of inequitable conduct — to the Patent and Trademark Office while attempting to "reissue" the Lemieux patent. Critikon also grossly misrepresents the legal standard stated and applied by the Federal Circuit.

I. Critikon Misrepresents The Evidence Relied Upon By The District Court

Critikon suggests that this trial presented a great contest of credibility on the issue of inequitable conduct between Critikon's *"witnesses"* (Cross-Petition at 4; emphasis added) and Becton Dickinson's technical expert, Mr. Fischell. The facts tell quite a different story.

Critikon did not present *any* witness at trial on the issue of inequitable conduct and offered no testimony on the McDonald patent.* The only trial testimony on this issue was that of Mr. Fischell, who testified that — unlike any prior art considered by the Examiner — McDonald disclosed Lemieux's point of novelty. That testimony was confirmed by Mr. Colletti's deposition testimony that he could not recall any prior art considered by the Examiner that disclosed those features. Critikon's technical expert, Mr. Vaillancourt,

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* Critikon objected to any cross-examination of its expert Mr. Vaillancourt on McDonald.

gave no testimony either challenging Mr. Fischell's conclusion or supporting Mr. Colletti's unfounded, conclusory characterization of the McDonald patent as "cumulative" of prior-art considered by the Examiner. Given the fact that Mr. Fischell's testimony concerning the materiality of the McDonald patent went unchallenged at trial, Critikon's current attempts to discredit him ring quite hollow.

II. Critikon Misrepresents The Reasons For The Federal Circuit's Reversal

Critikon claims that the Federal Circuit disregarded unspecified "credibility determinations" and "wrongly substituted its own interpretation of the facts" in reversing the District Court (Cross-Petition at 5-6, 10 and 11) is wrong. The District Court was reversed because it: (a) did not consider that the McDonald patent disclosed key features claimed by Lemieux; (b) did not consider evidence that Critikon failed to report this litigation during the reissue proceedings and (c) did not consider objective evidence that contradicted the "explanation" given by Mr. Yorks and Mr. Colletti for withholding the McDonald patent.

With respect to the District Court's error concerning the materiality of the McDonald patent, the Federal Circuit concluded that:

> The court apparently failed to recognize that although overall the Lemieux device may be substantially different from McDonald, the McDonald patent teaches two features, which the examiner considered central in the prosecution of the Lemieux patents (10a).

In reviewing the evidence concerning those features not considered by the District Court, the Federal Circuit found probative of McDonald's materiality: (a) the fact that the Examiner considered those features to be Lemieux's "point of novelty" (7a and 10a); (b) the fact that Mr. Colletti relied on those features to gain allowance of Lemieux's application (7a and 11a); and (c) Mr. Fischell's testimony that the

McDonald patent *alone* disclosed those features — a position "reflected" by Mr. Colletti's inability to recall any prior art considered by the Examiner that disclosed those features (10a-11a).

The Federal Circuit concluded that it was even more important (5a and 12a) that the District Court had erred by failing to consider both this litigation's materiality to the reissue proceedings (11a-12a) and Critikon's unexplained failure to report this litigation to the Patent and Trademark Office (8a). Plainly, no "credibility determinations" were rejected nor facts found *de novo* by the Federal Circuit's consideration of that evidence.

Finally, the Federal Circuit concluded that the District Court clearly erred in not considering objective evidence contradicting Mr. Yorks' and Mr. Colletti's "explanation" that they had withheld the McDonald patent because it was "cumulative" of prior art already before the patent Examiner (8a). That objective evidence included: (a) their intimate familiarity with the McDonald patent (7a); (b) the fact that they specifically relied on features disclosed in the McDonald patent to gain issuance of the Lemieux patent (7a-8a and 11a); (c) the fact that no prior art before the Examiner disclosed those features (10a-11a), and (d) the fact that Mr. Colletti "was repeatedly confronted with the McDonald patent and its significance over the course of the litigation, which substantially overlapped with the Lemieux reissue proceedings" (7a).

Contrary to Critikon's assertions, the Federal Circuit did not disregard the District Court's role as fact finder. Even assuming that the District Court had an opportunity to assess Mr. Yorks' and Mr. Colletti's "demeanor and tone of voice" (Cross-Petition at 11) — which it did not — where objective evidence contradicts a witness' story "the court of appeals may well find clear error even in a finding purportedly based on a credibility determination." *Anderson, supra* 470 U.S. at 575. This is particularly so in a case such as this where "the record does not reveal a single instance where Mr. Yorks or Mr. Colletti provided a good faith explanation"

for withholding the McDonald patent (8a) — and Critikon did not bring Mr. Yorks and Mr. Colletti to trial to provide one.

III. Critikon Misrepresents The Standard Applied By The Federal Circuit

Finally, Critikon makes several misrepresentations concerning the legal standard stated and applied by the Federal Circuit.

In *Kingsdown Med. Consultants, Ltd.* v. *Hollister Inc.*, 863 F.2d 867 (Fed.Cir. 1988), *cert. denied*, 490 U.S. 1067, 109 S.Ct. 2068 (1989) the Federal Circuit resolved "conflicting precedent regarding whether a finding of gross negligence *compels* a finding of intent to deceive" *Molins PLC* v. *Textron*, 48 F.3d 1172, 1181 n.11 (Fed.Cir. 1995) (emphasis added). *Kingsdown* adopted the holding in *FMC Corp.* v. *Manitowoc Co.*, 835 F.2d 1411 (Fed.Cir. 1987) that:

> an applicant who *knew or should have known* of the art or information, and of its materiality, is *not automatically* precluded thereby from an effort to convince the fact finder that . . . an inference of an intent to mislead is not warranted (*Id.* at 1416; emphasis added).

FMC nevertheless cautioned that:

> a patentee facing a high level of materiality and clear proof that it *knew or should have known* of that materiality, can expect to find it difficult to establish "subjective good faith" sufficient to prevent the drawing of an inference of intent to mislead. A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances (*Id.;* emphasis added).

See also LaBounty Mfg., Inc. v. *United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed.Cir. 1992).

Critikon first incorrectly states that *Kingsdown* rejected the rule that "wrongful intent *can* be found where an applicant 'should have known' that a reference was material"

(Cross-Petition at 6; emphasis added). That is not so. *Kingsdown* rejected the proposition set forth in *Driscoll* v. *Cebalo*, 731 F.2d 878 (Fed.Cir. 1984) that intent is *compelled* by a such a finding.

Second, Critikon incorrectly claims that the Federal Circuit "reverted to" and "resurrected" the *Driscoll* standard. On the contrary, the Federal Circuit correctly stated that:

> intent *may* be inferred where a patent applicant knew or should have known, that withheld information would be material to the PTO's consideration of the patent application (6a; emphasis added);

Indeed, the Federal Circuit applied *FMC's* cautionary note to Critikon: "Given the materiality and the failure at any point to offer a good faith explanation of the pattern of nondisclosure, an intent to mislead may be inferred" (9a and 12a). Indeed, "[a] relatively high degree of intent may be inferred" (6a).

Moreover, Critikon's claim that the Federal Circuit misapplied the law is belied by the fact that within weeks of entry of the Federal Circuit's opinion, Ethicon, Inc., an affiliate of Critikon at Johnson & Johnson, cited and quoted the Federal Circuit's opinion in this case *five times* in opposing a motion to strike an inequitable conduct defense *it* had raised. Indeed, Critikon's affiliate specifically relied on the Federal Circuit's application of the *FMC* standard:

> To overcome the inference of intentional deception, U.S. Surgical's witnesses must come forward with a "good faith explanation" sufficient to render the circumstances innocent. A "mere denial . . . will not suffice."*

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* *Ethicon, Inc.* v. *United States Surgical Corp.*, D.Conn., Civil No. B 89-386 (RNC) (August 27, 1997, Docket No. 788). Redacted portions of that memorandum are reproduced at 1a-6a, attached hereto.

REASONS FOR DENYING THE CONDITIONAL CROSS-PETITION

I. The Federal Circuit Properly Cited, Stated And Applied The Rule Of Law Set Forth In *FMC*

As discussed above, Critikon grossly misstates the legal standard used by the Federal Circuit in reversing the District Court's finding on intent. The Federal Circuit cited, stated and applied to the facts of record the standard of *FMC, supra:* that "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality" cannot prevent the drawing of an inference of intent to mislead by a mere denial of that intent. *FMC, supra* at 1416. The Federal Circuit's opinion neither stated or applied the proposition set forth in *Driscoll* that gross negligence compels a finding of inequitable conduct.

The entire basis for Critikon's first question presented is thus the Federal Circuit's *citation* of *Driscoll.* The fact that *Driscoll* does not stand for the accepted rule of law stated and applied by the Federal Circuit does not in any way undermine the Federal Circuit's opinion. Critikon's request that this Court consider the first question presented is meritless and should be denied.

II. The Federal Circuit Properly Performed Its Appellate Function In Reversing The District Court's Findings On Materiality And Intent

With respect to Critikon's second question presented, the Federal Circuit properly performed its appellate function in reversing the District Court's findings on materiality and intent. There is no basis for Critikon's claim that the "court below wholly disregarded the appropriate standard of review that governs all of the United States Courts of Appeals" (Cross-Petition at 12).

Rule 52(a), Fed.R.Civ.P., requires federal courts of appeal to accept findings of fact unless they are "clearly erroneous." A finding of fact is clearly erroneous when an appellate court "on the entire evidence is left with the definite and firm

conviction that a mistake has been committed." *Anderson, supra,* 470 U.S. at 573; *United States* v. *United States Gypsum,* 333 U.S. 364, 395, 68 S.Ct. 525 (1948). The Federal Circuit fully appreciated this standard:

> the court's ultimate determination is reviewed for abuse of discretion; the subsidiary factual questions are reviewed for clear error and are not to be disturbed unless we have a definite and firm conviction that a mistake has been committed. (5a; citation omitted).

A. The District Court Clearly Erred In Not Considering That McDonald Disclosed Lemieux's Point Of Novelty

The facts of record on appeal demonstrate that the McDonald patent disclosed features that the Examiner considered to be the "point of novelty" of Lemieux's invention. The evidence also showed that Critikon's attorneys relied on those specific features to gain allowance of the Lemieux patent and that no prior art before the examiner disclosed those features. The District Court made no findings to the contrary — let alone contrary findings based on credibility determinations.

Unable to dispute that evidence, Critikon's post-trial submissions urged the District Court to "consider the entirety of the subject matter claimed by Lemieux, and [not] a flawed 'point of novelty' approach." The District Court accepted that analysis, reviewed the evidence accordingly, and was persuaded that the McDonald patent "teaches a *device* that is substantially different than that contemplated by the Lemieux patents" (52a; emphasis added).

The definition of materiality, however, is not limited to a comparison of the claimed invention as a whole. "[I]nformation is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Gardco Mfg., Inc.* v. *Herst Lighting Co.,* 820 F.2d 1209, 1214 (Fed.Cir. 1987) (no error in "high-lighting the similarities between the fixtures"); *A.B. Dick Co.* v. *Burroughs Corp.,*

798 F.2d 1392, 1397 (Fed.Cir. 1986) (the reference did not disclose the "object" of the invention but did describe "the most important part of the system"). "[A]pplicants have a duty to disclose to the PTO information of which they are aware which is material to the examination of the application." 37 C.F.R § 1.56(a) (see 5a, 9a and 11a).

The District Court thus clearly erred by not considering the facts of record which established that the McDonald patent disclosed the point of novelty of the Lemieux patent. In considering the undisputed facts of record, the Federal Circuit did not reject any "credibility findings" or decide any factual issues *de novo.* On the contrary, the Federal Circuit's opinion gives guidance to trial courts by correcting the District Court's overly narrow view of materiality ("[a] device that operates differently . . . may nonetheless have relevant features" (11a)) and by illustrating the application of that proper standard to the undisputed facts of record.

B. The District Court Clearly Erred In Not Considering Critikon's Failure To Report This Litigation During The Reissue Proceedings

The District Court also clearly erred in not considering evidence concerning Critikon's failure to report the existence of this litigation (and the charge of inequitable conduct for failure to disclose the McDonald patent) to the Patent and Trademark Office during the proceedings to reissue the Lemieux patent. It is clear that Critikon's duty was not limited to disclosing prior art (37 C.F.R. § 1.56(a)) and it is self-evident that "litigation involving the patent in question would be relevant to the reissue proceeding" (11a). Again, the District Court made no finding to the contrary — let alone a finding based on credibility determinations.

Contrary to Critikon's suggestions, the Federal Circuit neither substituted "its own interpretation of the facts" (Cross-Petition at 10) nor decided any factual issues *de novo* in considering the complete *lack* of evidence of any good faith explanation for Critikon's failure to report this litigation to the Patent and Trademark Office. Again, the Federal

Circuit's opinion gives guidance to trial courts by correcting the District Court's overly narrow focus on Critikon's failure to disclose prior art — rather than "any material information" (11a).

C. The District Court Clearly Erred In Not Considering Objective Evidence Contradicting Critikon's "Explanation" For Withholding McDonald

Finally, the District Court clearly erred in accepting Critikon's "explanation" of why its attorneys withheld the McDonald patent from the Patent and Trademark Office. The record on appeal fully supports the Federal Circuit's reversal of the inference of good faith found by the District Court. The deposition "explanation" relied upon by the District Court is conclusory, unsupported by any corroborating evidence and directly contradicted by all the objective evidence on point.

Mr. Yorks gave no explanation. Mr. Colletti's conclusory claim that the McDonald patent was cumulative of other unidentified prior art was refuted by his admission that he could not recall any prior art *considered by the Examiner* that disclosed the retaining means used in the Lemieux device and by Critikon's refusal to permit Mr. Colletti to identify that "other" prior art. Moreover, that preposterous explanation is not due any greater deference because the District Court's did not assess Mr. Yorks' and Mr. Colletti's "demeanor" or "tone of voice" (Cross-Petition at 11). Critikon could have brought Mr. Yorks and Mr. Colletti and to testify at trial — but chose not to.

The Federal Circuit's detailed reasoning concerning the "explanation" given by Mr. Yorks and Mr. Colletti is a textbook implementation this Court's guidance in *Anderson,* 470 U.S. at 575:

> Documents or objective evidence may contradict the witness' story; or the story itself may be so internally inconsistent or implausible on its face that a reasonable factfinder would not credit it. Where such factors are present, the court of appeals may well find clear error even in a finding purportedly based on a credibility determination.

See also, United States v. *United States Gypsum Co.*, 333 U.S. at 396 ("[w]here such testimony is in conflict with contemporaneous documents we can give it little weight").*

CONCLUSION

For all the foregoing reasons, Critikon's conditional cross-petition for a writ of certiorari should be denied.

March 11, 1998

Respectfully submitted,

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* Critikon's reliance on the "sinister cast" language from *Inwood Lab., Inc.* v. *Ives Lab., Inc.*, 456 U.S. 844, 857-58, 102 S. Ct. 2182 (1982) is inapposite. The Court of Appeals was reversed in *Inwood* for making four separate *de novo* findings for which there was no support in the record. *Id.* at 856-57 n17-20.

CONFIDENTIAL — CONTAINS INFORMATION SUBJECT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

ETHICON, INC. and INBAE YOON, M.D., *Plaintiffs,*	:	
-against-	:	Civil Action No. B 89-386 (RNC)
UNITED STATES SURGICAL CORPORATION, *Defendant,*	:	August 22, 1997
-and-	:	
YOUNG JAE CHOI, *Intervenor-Defendant.*	:	

ETHICON'S MEMORANDUM OF LAW IN OPPOSITION TO USSC'S MOTION FOR SUMMARY JUDGMENT STRIKING ETHICON'S AFFIRMATIVE DEFENSE OF INEQUITABLE CONDUCT

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I. THE STANDARD FOR INEQUITABLE CONDUCT

The standard of proof for inequitable conduct is intentionally set high, but in that regard it parallels the high standard of disclosure placed on applicants in the Patent Office. Applicants are intentionally held to a rigorous obligation of candor and, when they fall short, the Federal Circuit has not hesitated to declare unenforceable patents obtained by deceptive conduct. *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.*, No. 95-1322 (Fed. Cir. Aug. 12, 1997) at p. 4 (attached to the Pippert Declaration as Exhibit 45); *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993).

Indeed, the doctrine rendering patents unenforceable if obtained by inequitable conduct is essential to protect the integrity of the patent system. The patent examiner deals with the applicant *ex parte*. He has limited resources and no ability to engage in independent investigation. Accordingly, the examiner must depend upon full and complete disclosure from the applicant. As the predecessor to the Federal Circuit, the Court of Customs and Patent Appeals, explained years ago in language that has been repeatedly endorsed over time:

> The ex parte prosecution and examination of a patent application must not be considered as an adversary proceeding and should not be limited to the standards required in inter partes proceedings. With the seemingly ever-increasing number of applications before it, the Patent Office has a tremendous burden. While being a fact-finding as well as an adjudicatory agency, it is necessarily limited in the time permitted to ascertain the facts necessary to adjudge the patentable merits of each application. In addition, it

> has no testing facilities of its own. Clearly it must rely on applicants for many of the facts upon which its decisions are based. The highest standards of honesty and candor on the part of applicants in presenting such facts to the office are thus necessary elements in a working patent system. We would go so far as to say they are essential.

Norton v. Curtiss, 433 F.2d 779, 793-94 (CCPA 1970)

The duty of candor is set forth by regulation, 37 C.F.R. § 1.56, and it is regularly emphasized — and enforced — by the courts. Just within the past two weeks the Federal Circuit has again reiterated this fundamental obligation of the patentee: "It is axiomatic that '[c]lose cases should be resolved by disclosure, not unilaterally by the applicant.'" *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.,* at p. 8 (Pippert Decl. Ex. 45), *quoting LaBounty Mfg., Inc. v. United States Int'l Trade Commission,* 958 F.2d at 1066, 1076 (Fed. Cir. 1992).

Inequitable conduct must be proved by clear and convincing evidence. Proof of two elements is required: materiality and intent to deceive.

> The doctrine of inequitable conduct requires a trial court to undertake a two-step analysis. The trial court must discern whether the withheld references satisfy a threshold level of materiality. The court must also determine whether the applicant's conduct satisfies a threshold showing of intent to mislead.

Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d at 1435, 1439 (Fed. Cir. 1991); *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.,* 863 F.2d 867, 872 (Fed. Cir. 1988). Once these threshold showings have been made, the court must then balance the elements to determine whether inequitable conduct occurred. "The more

material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.*, at p. 5 (Pippert Decl. Exhibit 45); *Akzo v. the United States Int'l Trade Commission*, 808 F.2d 1471, 1478 (Fed. Cir. 1986). In this regard, the Court will scrutinize the conduct of the applicant, the assignee and the attorneys. *Molins PLC v. Textron*, 48 F.3rd 1172, 1178 note 6 (Fed. Cir. 1995).

"Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances." *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.* at p. 6 (Pippert Decl. Ex. 45).

To overcome the inference of intentional deception, U.S. Surgical's witnesses must come forward with a "good faith explanation" sufficient to render the circumstances innocent. A "mere denial . . . will not suffice." *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.* at p. 8 (Pippert Decl. Ex. 45). *Cf. Paragon,* 984 F.2d at 1191 (declaration of lack of intent to mislead insufficient to create a genuine issue of fact to avoid summary judgment).

Supreme Court, U.S.
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MAR 31 1998
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No. 97-1292

In The

Supreme Court of the United States

October Term, 1997

CRITIKON, INC.,

Cross-Petitioner,

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,

Cross-Respondent.

On Conditional Cross-Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY IN SUPPORT OF CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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REPLY TO OPPOSITION

The importance of the first question presented in Critikon's conditional cross-petition for a writ of certiorari, namely, the correct legal standard governing whether a patent applicant can be found guilty of inequitable conduct, *i.e.*, by committing fraud on the PTO, is not denied by Becton Dickinson. Nor does Becton Dickinson deny that this legal question is squarely presented by the facts of this case. And importantly, Becton Dickinson's opposition highlights the hopeless state of confusion created by the Federal Circuit's decision in *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed.Cir. 1997), on the issue of inequitable conduct. For all of these reasons, this Court should grant certiorari to address the proper legal standard governing the adjudication of a charge of inequitable conduct, a charge that occurs in nearly every patent infringement action.

A. Confusion Exists As To What Is Required To Support A Finding Of Inequitable Conduct

As Critikon established in its petition, old Federal Circuit cases, such as *Driscoll v. Cebalo*, 731 F.2d 878 (Fed.Cir. 1984), held that negligence on the part of a patent applicant was sufficient to support a finding of inequitable conduct. Under the rule of *Driscoll*, a patent applicant could be found guilty of inequitable conduct – fraud on the PTO – if he was merely negligent in his dealings with the PTO. 731 F.2d at 885.

Later, the Federal Circuit thoroughly revisited this issue in its *en banc* decision in *Kingsdown Medical Consultants v. Hollister Inc.*, 863 F.2d 867 (Fed.Cir. 1988). In

Kingsdown, as Becton Dickinson concedes, the Federal Circuit squarely rejected the negligence standard of *Driscoll*. 863 F.2d at 876. Specifically, the *Kingsdown* court held that the finding of even "gross" negligence is insufficient to support a finding of inequitable conduct. 863 F.2d at 876. Thus, the rule of *Driscoll* has long been thought to be thoroughly discredited.

The central problem here that calls for this Court's attention is the Federal Circuit's apparent revival of *Driscoll* as controlling law, throwing the rule of law governing the adjudication of a charge of inequitable conduct into a state of utter confusion. Thus, as matters now stand, no one knows what the controlling law is – the rule of *Driscoll*, long thought to be discredited but now apparently resurrected by the *Critikon* panel, or the rule of *Kingsdown* that has been in place for nearly a decade.

It is telling that Becton Dickinson essentially ignores the Federal Circuit's citation to *Driscoll v. Cebalo*, 731 F.2d 878 (Fed.Cir. 1984). Certainly, there can be no doubt that the *Critikon* panel, in citing *Driscoll*, appeared to revive the "negligence" standard for determining whether a patent applicant can be found guilty of inequitable conduct. 120 F.3d at 1256. Unquestionably, as the Federal Circuit stated in *Critikon*:

> For example, intent may be inferred where a patent applicant . . . *should have known* [ ] that withheld information would be material. . . . *Driscoll v. Cebalo*, 731 F.2d 878, 885, 221 USPQ 745, 751 (Fed.Cir. 1984).

Id. (emphasis added).

B. Becton Dickinson's Opposition Exemplifies The Confusion That Exists In The Law

In an attempt to prop up the *Critikon* decision, Becton Dickinson essentially argues that when the *Critikon* panel cited to *Driscoll* on the level of wrongful intent required for a finding of inequitable conduct, it really intended to cite *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411 (Fed.Cir. 1987). (Opposition at 11). This alleged misunderstanding over what authorities the Federal Circuit intended to rely on itself shows that the *Critikon* decision has generated hopeless uncertainty in the law. Moreover, even if the *Critikon* panel meant to apply the holding of *FMC*, rather than that of *Driscoll*, as it said it did, Becton Dickinson's argument fails because the Federal Circuit in *Kingsdown*, along with its rejection of *Driscoll*, thoroughly rejected the *FMC* legal standard for adjudicating the issue of inequitable conduct. 863 F.2d at 876.

In an attempt to support the revival of the negligence standard, Becton Dickinson creates even more confusion by pointing to the language in *Kingsdown* that "gross negligence alone *does not mandate* a finding of intent to deceive." *Kingsdown*, 865 F.2d at 876 (emphasis added). According to Becton Dickinson, this language left open the possibility that the necessary level of wrongful intent could be based on – but was not mandated by – a finding of negligence on the part of the patent applicant. (Opposition at 9-10). The *Kingsdown* court, however, put this possibility to rest in the very next paragraph of the opinion when it unequivocally held that "gross negligence *does not*" justify an inference of an intent to deceive. *Kingsdown*, 863 F.2d at 876 (emphasis added). Plainly, the

argument that *Critikon* overruled this long settled rule of *Kingsdown* is yet another ground for confusion.

C. This Petition Presents A Purely Legal Question

Becton Dickinson's long discussion of the facts of this case is makeweight. The central question presented by Critikon is purely a legal question, and it is one that Becton Dickinson does not deny is presented by the facts of this case. Thus, Becton Dickinson's discussion of the facts is irrelevant to the critical issue here, namely, whether the Federal Circuit's decision in *Critikon* adopted the proper legal standard to decide whether a patent applicant committed inequitable conduct in the PTO.

D. The Undisputed State Of Uncertainty In The Law Presents A Compelling Reason For Granting This Petition

In sum, the abrupt and unexplained change in direction of the *Critikon* panel has created a state of uncertainty in the law. This uncertainty affects inventors and investors, as well as the public that can attain significant benefits from costly and risky research and development that hinges on the ability to obtain sound, enforceable patent protection. *See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, ___ U.S. ___, ___, 117 S.Ct. 1040, 1045 (1997). In the presence of the confusion created by the *Critikon* decision and in the absence of this Court's action, research and development that depends on sound patent protection will be shelved to the public's detriment.

CONCLUSION

For the foregoing reasons, Critikon's conditional cross-petition for a writ of certiorari should be granted.

Respectfully submitted,

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